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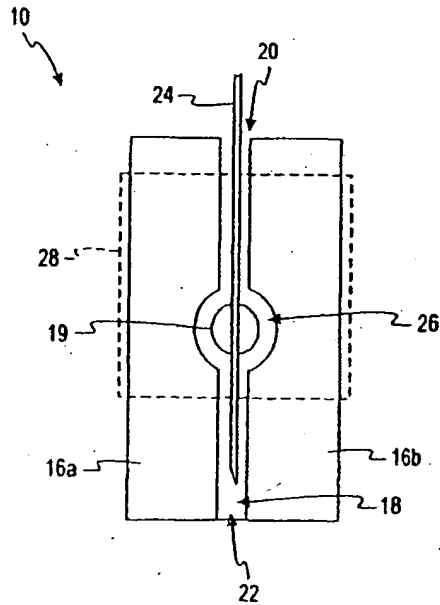
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(54) **Sensor with integrated lancet**

(57) A fluid collection apparatus adapted to test a concentration of an analyte in a fluid, including a lid and a base. Further included is a spacer disposed between the lid and the base. The spacer forms a capillary channel, which has an opening and is designed to collect the fluid. The capillary channel includes a reagent that reacts with the fluid to produce a measurable reaction. The reaction will provide a measurable indication of the concentration of the analyte in the fluid. Coupled to the lid is a lancet that is moveable to the base and is moveable to a position adjacent the opening of the capillary channel.



**FIG. 6**

**Description****FIELD OF THE INVENTION**

[0001] The present invention relates generally to blood monitoring devices and, more particularly, to a sensor having an integrated lance.

**BACKGROUND OF THE INVENTION**

[0002] It is often necessary to quickly obtain a sample of blood and perform an analysis of the blood sample. One example of a need for quickly obtaining a sample of blood is in connection with a blood glucose monitoring system where a user must frequently use the system to monitor the user's blood glucose level.

[0003] Those who have irregular blood glucose concentration levels are often medically required to self-monitor their blood glucose concentration level. An irregular blood glucose level can be brought on by a variety of reasons including illness, such as diabetes. The purpose of monitoring the blood glucose concentration level is to determine the blood glucose concentration level and then to take corrective action, based upon whether the level is too high or too low, to bring the level back within a normal range. The failure to take corrective action can have serious implications. When blood glucose levels drop too low, a condition known as hypoglycemia, a person can become nervous, shaky, and confused. That person's judgment may become impaired and that person may eventually pass out. A person can also become very ill if their blood glucose level becomes too high, a condition known as hyperglycemia. Both conditions, hypoglycemia and hyperglycemia, are potentially life-threatening emergencies.

[0004] One method of monitoring a person's blood glucose level is with a portable, hand-held blood glucose testing device. A prior art blood glucose testing device 100 is illustrated in FIG. 1. The portable nature of these devices 100 enables the users to conveniently test their blood glucose levels wherever the user may be. The glucose testing device contains a test sensor 102 to harvest the blood for analysis. The device 100 contains a switch 104 to activate the device 100 and a display 106 to display the blood glucose analysis results. In order to check the blood glucose level, a drop of blood is obtained from the fingertip using a lancing device. A prior art lancing device 120 is illustrated in FIG. 2. The lancing device 120 contains a needle lance 122 to puncture the skin. Some lancing devices implement a vacuum to facilitate drawing blood. Once the requisite amount of blood is produced on the fingertip, the blood is harvested using the test sensor 102. The test sensor 102, which is inserted into a testing unit 100, is brought into contact with the blood drop. The test sensor 102 draws the blood to the inside of itself. The test sensor, in combination with the testing unit, then determines the concentration of glucose in the blood. Once the results of the test are

displayed on the display 106 of the test device 100, the test sensor 102 is discarded. Each new test requires a new test sensor 102.

[0005] One problem associated with current test devices is that the test device comprises a two step operation for sample generation and sample harvesting/reading. The two operations are accomplished with two separate instruments (a lance and a test sensor), each having a separate disposable. This requires more parts and more work for the user in disposing the parts.

[0006] Another problem associated with current test devices is the difficulty in harvesting small samples when the test sensor is separate from the lance. There is a trend in glucose testing towards minimizing the sample volume. This trend is based on the assumption that there is a corresponding reduction in pain when less sample volume is acquired. As the sample volume is reduced, it becomes more difficult to manually manipulate the test sensor in order to harvest the blood. This is especially true for people who may have seeing impairments or other disabilities, making it difficult to manipulate the test sensor within a small area.

[0007] Another problem associated with obtaining small sample sizes is related to the precision needed to obtain the samples. When only small amounts of blood are produced by the lance, it is important that the entire sample or most of the sample be drawn into the test device. When larger volumes of blood are drawn, it is less necessary to obtain all of the blood for the sensor. In small volume test devices, it is important that the sensor be located very near to the puncture wound to maximize the amount of blood that is drawn into the sensor for testing. In current test devices, where the sensor has to be manually moved to the puncture wound, it may be difficult to get close enough to the wound to obtain enough of the sample.

[0008] Some current test devices utilize an integrated sensor and lance. The lance is perpendicular to the plane of the test sensor and penetrates through the sensor surface. These sensors, however, still experience the problem that the test sensor must be manually manipulated after the lancing operation is performed.

[0009] Another test device has been developed for the collection of interstitial fluid (ISF) that utilizes an integrated lance and reaction area. ISF is collected by piercing just below the skin before any nerve endings or any capillaries. Collecting ISF is sometimes desirable because there is no pain involved since it is above any nerve endings. The lance in this test device is not strong enough to pierce through the dermal layer of the skin in order to obtain samples of other fluids, such as blood. One disadvantage of this and other integrated systems is that the user is forced to dispose of the lance with each test device, an additional expense, as most users reuse their lancets a number of times. A second disadvantage is that any reagent in the device is necessarily exposed to extreme conditions during the required sterilization of the lance. Such exposure may affect the per-

formance of the device.

#### SUMMARY OF THE INVENTION

[0010] The present invention is a fluid collection apparatus adapted to test a concentration of an analyte in a fluid and includes a lid and a base. The fluid collection apparatus further includes a spacer disposed between the lid and the base. The spacer forms a capillary channel, which has an opening and is designed to collect the fluid. The capillary channel also includes a reagent that reacts with the fluid to produce a measurable reaction. The reaction will indicate the concentration of the analyte in the fluid. Coupled to the lid is a lance that is moveable to the base and is moveable to a position adjacent the opening of the capillary channel.

[0011] The above summary of the present invention is not intended to represent each embodiment, or every aspect, of the present invention. This is the purpose of the figures and the detailed description which follow.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The foregoing and other advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings.

FIG. 1 is a top view of a prior art blood glucose testing device.

FIG. 2 is a perspective view of a prior art lance.

FIG. 3 is a top end view of a test device according to one embodiment of the present invention.

FIG. 4a is a front view of a test device having a cover removed according to one embodiment of the present invention.

FIG. 4b is a front view of a test device having a cover removed according to another embodiment of the present invention.

FIG. 5 is a side view of a test device according to one embodiment of the present invention.

FIG. 6 is a top view of the test device of FIG. 5.

FIG. 7 is top view of the test device according to another embodiment of the present invention.

[0013] While the invention is susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. It should be understood, however, that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

#### DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0014] FIG. 3 depicts a fluid collection apparatus 10 according to one embodiment of the present invention.

The fluid collection apparatus 10 is designed to collect a fluid, such as blood, so the fluid may be tested for the concentration of a particular analyte, such as glucose. In describing the details of the operation of the fluid collection apparatus 10, the fluid described will be blood pricked from a finger and the analyte will be glucose. It is understood that the embodiment may also be used for other fluids and analytes and that these only serve as examples.

[0015] The fluid collection apparatus 10 includes a lid 12, a base 14, and a pair of spacers 16a, 16b disposed between the lid 12 and the base 14. The pair of spacers 16a, 16b form a capillary channel 18. In the illustrated embodiment, the capillary channel 18 is elongated and spans the entire length of the spacers (shown in FIG. 4a). The capillary channel 18 has a first end 20 and a second end 22 (shown in FIG. 4a). The capillary channel 18 includes a reagent 19 that will react with the drawn blood in order to create a measurable reaction. According to one embodiment, the reagent 19 is disbursed throughout the entire capillary channel. A lance 24 is disposed in the capillary channel 18. The lance 24 is moveable through the capillary channel 18 in a direction parallel to the length of the capillary channel 18.

[0016] In one embodiment, the fluid collection apparatus 10 can be used in conjunction with a photometric test device to measure the concentration of the analyte directly, for example, by the absorption of light in the infrared region. The test device would measure the amount of infrared light absorbed. Alternatively, a reagent 19 can be used that causes a change in color in the capillary channel. The photometric test device then reads the amount of color change. Photometric testing is described in more detail in commonly-owned U.S. Patent No. 5,611,999 entitled "Diffuse Reflectance Readhead" which is incorporated herein by reference in its entirety. It is also contemplated that other methods of measuring the concentration of glucose in blood may be utilized.

[0017] In another embodiment of the fluid collection apparatus 10, an electrochemical test device is employed as shown in FIG. 4b. The capillary channel 18 includes a pair of electrodes 25. In electrochemical analysis, the change in current across the electrodes 25 caused by the reaction of the glucose and the reagent 19 creates an oxidation current at the electrodes 25 which is directly proportional to the user's blood glucose concentration. The current can be measured by an electrochemical test device coupled to a pair of terminals (not shown) corresponding to the electrodes 25. The electrochemical test device can then communicate to the user the blood glucose concentration. An example of an electrochemical test system is described in detail by commonly-owned U.S. Patent No. 5,723,284 entitled "Control Solution And Method For Testing The Performance Of An Electrochemical Device For Determining The Concentration Of An Analyte In Blood" which is incorporated herein by reference in its entirety.

[0018] Turning now to FIG. 4a, a top view of the fluid collection apparatus 10 with the lid 12 removed is shown. As can be seen in this view, the lance 24 extends through the capillary channel 18 and out of the first end 20. The reagent 19 may be placed anywhere within the capillary channel 18.

[0019] In FIG. 4b, an alternative embodiment of the fluid collection apparatus 10 is shown. In this embodiment, the capillary channel 18 includes a detection area 26. The detection area 26 may be a reaction area that includes the reagent 19 and is slightly wider than the rest of the capillary channel 18. The enlarged area makes viewing easier and is used with some optical sensors.

[0020] In one embodiment, the capillary channel 18 is from approximately 0.020 to approximately 0.040 inches in length and from approximately 0.006 to approximately 0.012 inches in width. The lance 24 is from approximately 0.005 to approximately 0.011 inches in diameter. The detection area 26 has an area of approximately  $0.7 \times 10^{-3}$  to approximately  $10 \times 10^{-3}$  inches squared.

[0021] The operation of the device 10 illustrated in the embodiments of FIGS. 3-4b will now be described. A user will position the apparatus such that the second end 22 of the capillary channel 18 is pressed against the skin. The lance 24 is in a first position, shown in FIG. 4a, extending out from the first end 20 of the capillary channel 18. The user then pushes the lance 24 downward to a second position shown in FIG. 4b, such that the lance 24 extends past the second opening 22 of the capillary channel 18 and enters the skin. The lance 24 is pushed downward with enough force to create a puncture wound sufficient to draw blood. The lance 24 has a length greater than the capillary channel 18, allowing the lance 24 to extend past both the first and the second ends 20, 22 of the capillary channel 18. Once the lance 24 has punctured the skin, the user pulls lance 24 out of the skin and up the capillary channel 18, at least past the reaction area 26. Blood is drawn into the capillary channel 18 via capillary action. The reagent 19 in the capillary channel 18 reacts with the blood to create a reaction that can be measured as discussed above. In some embodiments, the capillary channel 18 includes stops (not shown) that prevent the lance 24 from being completely pulled out of the capillary channel 18. In these embodiments, it is only necessary to pull the lance past the location of the reagent 19.

[0022] The fluid collection apparatus 10 as described provides the advantage of placing the harvesting or collection point of the sensor at the same location as the puncture wound from the lance 24. This eliminates the need to move the fluid collection apparatus 10 around after drawing blood in order to harvest the blood. The device 10 is easier to use, because the users will not have to manually manipulate the sensor after the puncture by trying to place the sensor at the precise location of the puncture.

[0023] Turning now to FIGS. 5 and 6, another embodiment of the present invention will be shown. Like reference numerals will be used to identify like structures. In this embodiment, the fluid collection apparatus 10 includes the base 14, the pair of spacers 16a, 16b, the capillary channel 18 that is defined by the spacers 16a, 16b, the lid 12, and the lance 24. Alternatively, the base and the spacers or the lid and the spacers can be combined into a single piece that has been molded or formed to this three dimensional shape. In the embodiment shown in FIG. 6, the fluid collection apparatus 10 includes a detection area 26. The detection area 26 may be a specific reaction area including the reagent 19. Alternatively, the reagent 19 is dispersed throughout the entire capillary channel 18. In another embodiment, there is no reagent and an infrared detector may be used to measure the absorption of infrared light.

[0024] The collection apparatus 10 also includes a guide 28 for moving the lance. The guide 28 is slidably engaged to the base 14, the spacers 16a, 16b, or the lid 12. The guide 28 is moveable in a direction parallel to the length of the capillary channel 18. The guide 28 is attached to the lance 24. In this embodiment, the lance 24 is not disposed inside the capillary channel 18 but, instead, is adjacent to the capillary channel 18.

[0025] The lance 24 is disposed so that it will draw blood at a location adjacent to the second end 22 of the capillary channel 18. The lance 24 may be located at an angle relative to the capillary channel 18 (such as shown in another alternative embodiment depicted in FIG. 7) or it may be located directly above the capillary channel 18 (shown in FIGS. 5 and 6). Other embodiments are contemplated having the second end 22 of the capillary channel 18 adjacent to the puncture wound, but having different orientations for the lance 24 and the capillary channel 18.

[0026] Returning now to the description relating to FIGS. 5 and 6, the guide 28 is used to move the lance 24 between the first and second positions shown in FIGS. 4a and 4b. When in the second position, the lance will pierce the skin for drawing blood, creating a puncture wound. Because the second end 22 of the capillary channel 18 is adjacent to the puncture wound, blood will flow from the wound into the capillary channel 18 via capillary action without any manual moving of the fluid collection apparatus 10. In this embodiment, the lance 24 only needs to be pulled out of the skin, but does not need to be pulled completely out of the capillary channel 18, since the lance's location will not prevent the blood from entering the capillary channel 18. Since the guide 28 is wider than the lance 24, the guide 28 may be easier for some users to grasp and use than the prior embodiment.

[0027] Turning now to FIG. 7, another embodiment of the present invention will be described. In this embodiment, the lance 24 is disposed in a lance channel 30, having a first end 32 and a second end 34. The lance channel 30 is formed by first and second spacers 16a,

16b. The capillary channel 18 is formed by the second spacer 16b and a third spacer 16c. The lance 24 is moveable within the lance channel 30 in a direction parallel to the length of the channel 30. The lance channel 30 is disposed such that the second end 34 of the lance channel 30 is adjacent to the second end 22 of the capillary channel 18.

[0028] In operation, the fluid collection apparatus 10 is placed against the skin as in the other embodiments. The lance 24 is then pushed downward through the lance channel 30 and into the skin. After the skin is punctured, the lance 24 is withdrawn from the skin, but remains within the lance channel 30. The blood is then drawn into the capillary channel 18, via capillary action. By keeping the lance 24 in the lance channel 30, the lance channel 30 is not able to draw any blood into it, and all of the blood is instead drawn into the adjacent capillary channel 18. Alternatively, at least one face of the lance channel 30 can be of a hydrophobic material that inhibits entry of the blood into the lance channel 30.

[0029] In the illustrated embodiment, the capillary channel 18 includes the detection area 26. In this embodiment, the reagent 19 is kept in the detection area 26, creating the measurable reaction in the detection area 26. In some embodiments, there will not be a specific, enlarged detection area 26 and the reagent 19 will be dispersed elsewhere in the capillary channel 18.

[0030] While the present invention has been described with reference to one or more particular embodiments, those skilled in the art will recognize that many changes may be made thereto without departing from the spirit and scope of the present invention. Each of these embodiments and obvious variations thereof is contemplated as falling within the spirit and scope of the claimed invention, which is set forth in the following claims.

#### Claims

1. A fluid collection apparatus to test a concentration of an analyte in a fluid, comprising:

a lid;  
 a base having a plane;  
 a spacer disposed between said lid and said base, said spacer including a capillary channel having an opening for receiving the fluid; and  
 a lance disposed between said lid and said base, said lance moveable relative to said base and parallel to said plane of said base, said lance having a piercing end that is moveable to a position adjacent said opening of said capillary channel, said lance extending beyond said lid and said base for puncturing.

2. The fluid collection apparatus of claim 1, wherein said lance is coupled to a guide for moving said

lance.

3. The fluid collection apparatus of claim 1, wherein said lance is disposed in said capillary channel.

4. The fluid collection apparatus of claim 1, wherein said capillary channel is elongated and said lance is disposed in said elongated capillary channel, such that said lance is moveable along the length of said capillary channel between a first position and a second position.

5. The fluid collection apparatus of claim 1, further comprising an elongated lancing channel having an end adjacent to said opening of said capillary channel, wherein said lance is disposed in said lancing channel.

6. The fluid collection apparatus of claim 1, wherein said capillary channel has a length of approximately 0.020 to approximately 0.040 inches.

7. The fluid collection apparatus of claim 1, wherein said capillary channel includes a detection area for containing a reagent adapted to produce a reaction indicative of the concentration of the analyte in the fluid.

8. The fluid collection apparatus of claim 7, wherein said detection area has an area of approximately  $0.7 \times 10^{-3}$  to  $10 \times 10^{-3}$  inches squared.

9. The fluid collection apparatus of claim 1, wherein said capillary channel has a width of approximately 0.006 to approximately 0.012 inches.

10. The fluid collection apparatus of claim 1, wherein said lance has a diameter of approximately 0.005 to approximately 0.011 inches.

11. The fluid collection apparatus of claim 1, further comprising a reagent disposed in said capillary channel and adapted to produce a reaction indicative of the concentration of the analyte in the fluid.

12. The fluid collection apparatus of claim 11, wherein the reagent is adapted to produce a colorimetric reaction.

13. The fluid collection apparatus of claim 12, in combination with a colorimetric test device.

14. The fluid collection apparatus of claim 11, wherein the reagent is adapted to produce an electrochemical reaction.

15. The fluid collection apparatus of claim 14, in combination with an electrochemical test device.

16. The fluid collection apparatus of claim 1, wherein the analyte is glucose.
17. The fluid collection apparatus of claim 16, in combination with a test device adapted to measure the concentration of glucose in blood.
18. The fluid collection apparatus of claim 1, in combination with a test device adapted to measure the absorption of infrared light by the fluid.
19. A fluid collection apparatus adapted to test a concentration of an analyte in a fluid, comprising:
- a lid;
  - a base having a plane;
  - a spacer disposed between said lid and said base, said spacer including an elongated capillary channel for receiving the fluid; and
  - a lance disposed in said capillary channel and moveable parallel to said base of said plane and in between a first position and a second position along the length of said capillary channel.
20. The fluid collection apparatus of claim 19 wherein said capillary channel includes a reagent adapted to produce a reaction indicative of the concentration of the analyte in the fluid.
21. A fluid collection apparatus adapted to test a concentration of an analyte in a fluid, comprising:
- a lid;
  - a base;
  - a spacer disposed between said lid and said base, said spacer including a capillary channel and a lance chamber, said capillary channel having an opening adjacent to an opening of said lance chamber; and
  - a lance disposed in said lance chamber, said lance being moveable in said lance chamber such that said lance moves parallel to a plane of said base.
22. The fluid collection apparatus of claim 21, wherein said lance channel is unable to collect fluid.
23. The fluid collection apparatus of claim 21, wherein said lance channel includes at least one face, said lance channel is of a hydrophobic material.
24. The fluid collection apparatus of claim 21, wherein said capillary channel is adapted to collect the fluid, said capillary channel including a reagent adapted to produce a reaction indicative of the concentration of the analyte in the fluid.
25. A fluid collection apparatus adapted to test a concentration of an analyte in a fluid, comprising:
- a base;
  - a guide;
  - a pair of spacers disposed between said base and said guide, said pair of spacers defining a capillary channel having an opening; and
  - a lance coupled to said guide, such that a movement of said guide causes a movement of said lance parallel to a plane of said base, an end of said lance moveable to a position adjacent to said opening of said capillary channel;
- wherein said capillary channel is adapted to collect the fluid, said capillary channel including a reagent adapted to produce a reaction indicative of the concentration of the analyte in the fluid.
26. The fluid collection apparatus of claim 25, wherein said lance is disposed directly above said capillary channel.
27. The fluid collection apparatus of claim 25, wherein said lance is disposed at an acute angle relative to said capillary channel.
28. The fluid collection apparatus of claim 25, wherein said lance is moveable between a first position and a second position.
29. A method for testing a concentration of glucose in a user's blood utilizing a fluid collection apparatus having an integrated lance and a capillary channel located in the same plane, the method comprising:
- placing an end of the capillary channel against the user's skin;
  - pushing the lance into the skin so as to puncture the skin and draw blood;
  - pulling the lance out of the skin;
  - drawing the blood into the capillary channel without moving the fluid collection apparatus;
  - and
  - measuring the amount of glucose in the blood.
30. The method of claim 29, wherein the lance is disposed in the capillary channel and the step of pulling the lance out of the skin further comprises pulling the lance out of the capillary channel.
31. The method of claim 29, wherein the lance is disposed in the capillary channel and the step of pulling the lance out of the skin further comprises pulling the lance past the end of the capillary channel.
32. The method of claim 31, wherein the step of pulling the lance past the end of the capillary includes pull-

ing the lance past a reagent in the capillary channel.

33. The method of claim 29, wherein the capillary channel includes a detection area adapted to store a reagent adapted to react with the blood. 5
34. The method of claim 29, further comprising reacting the blood with a reagent in the capillary channel.
35. The method of claim 34, wherein the step of reacting the blood with the reagent creates a colorimetric reaction. 10
36. The method of claim 34, wherein the step of reacting the blood with the reagent creates an electrochemical reaction. 15

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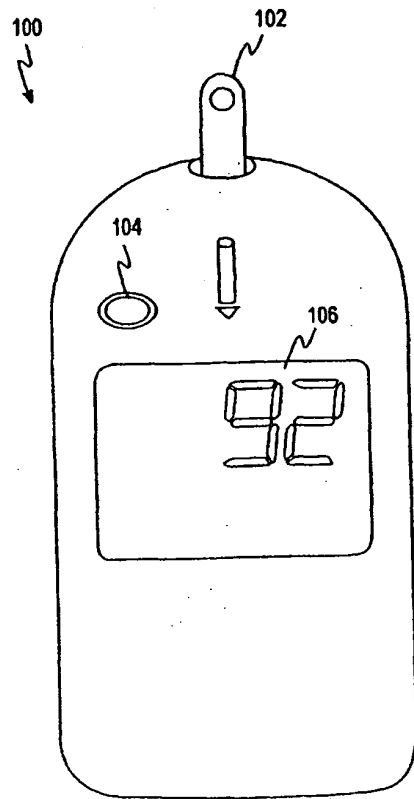


FIG. 1  
(Prior Art)



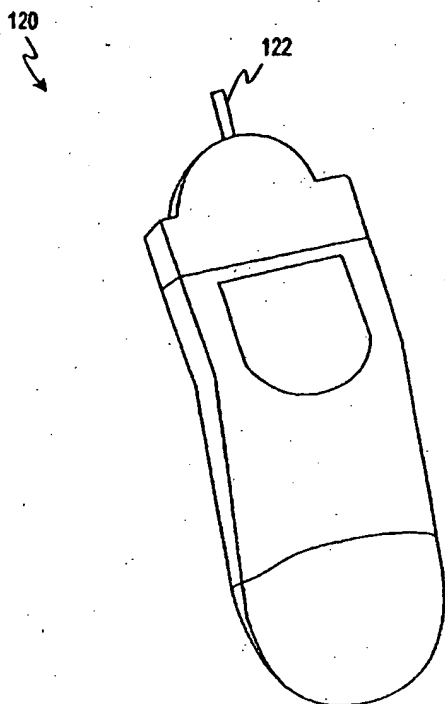


FIG. 2  
(Prior Art)

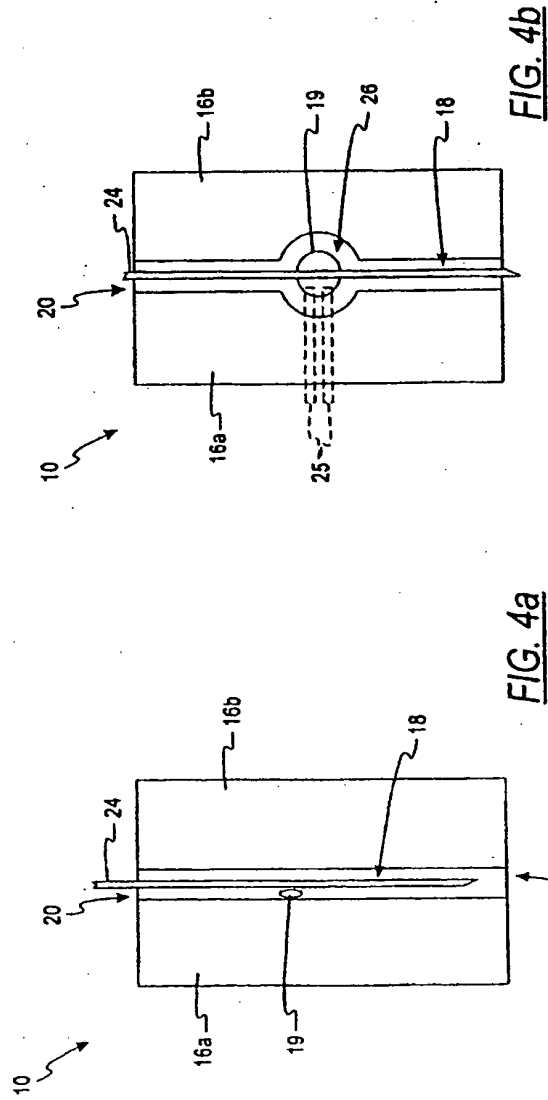


FIG. 4b

FIG. 4a

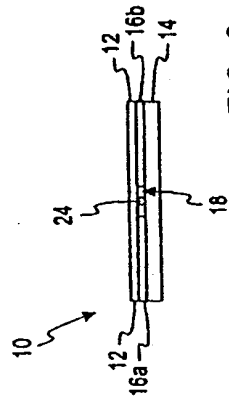


FIG. 3

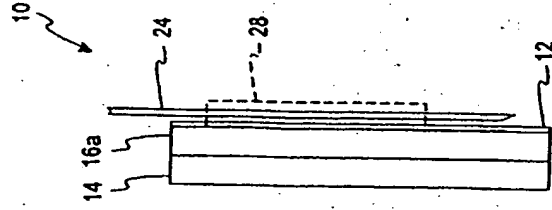


FIG. 5

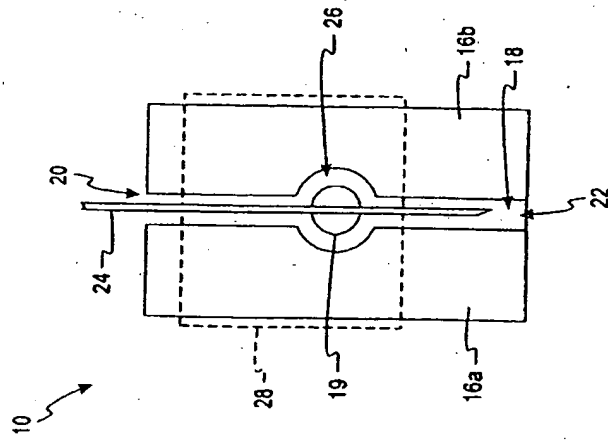


FIG. 6

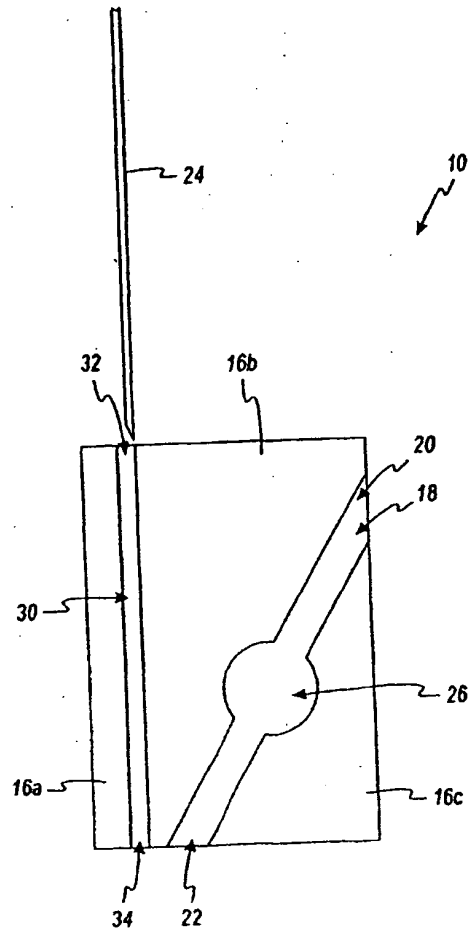


FIG. 7



European Patent Office

**PARTIAL EUROPEAN SEARCH REPORT**

Application Number

which under Rule 45 of the European Patent Convention EP 03 01 4233 shall be considered, for the purposes of subsequent proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 4 627 445 A (GARCIA FERNANDO S ET AL) 9 December 1986 (1986-12-09) * column 5, line 17 - column 12, line 44; figures 9,13,15 *	1-5,7, 11-21, 24-28	A61B5/15 A61B10/00
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A	US 6 132 449 A (FREEMAN DOMINIQUE M ET AL) 17 October 2000 (2000-10-17) * column 2, line 45 - column 3, line 29 *	1-28	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61B
<b>INCOMPLETE SEARCH</b>			
The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.			
Claims searched completely : 1-28			
Claims searched incompletely :			
Claims not searched : 29-36			
Reason for the limitation of the search: Article 52 (4) EPC - Method for treatment of the human or animal body by surgery			
Place of search MUNICH		Date of completion of the search 2 September 2003	Examiner Rivera Pons, C
CATEGORY OF CITED DOCUMENTS			
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EP 1 374 770 A1

ANNEX TO THE EUROPEAN SEARCH REPORT  
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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.  
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